

### **REMARKS**

Applicants have carefully reviewed the Office Action dated November 14, 2005 regarding the above-referenced patent application. Claims 1-32 are pending, claims 11-16 and 27-32 have been withdrawn from consideration and claims 1-10 and 17-26 have been rejected. Claims 1 and 3 have been amended with this response.

Claims 1 and 8-10 were rejected based on 35 U.S.C. §102(e) as being anticipated by Palmer et al., U.S. Patent No. 6,638,294 (hereinafter "Palmer"). Applicant respectfully traverses this rejection. In order for a reference to anticipate a claim, each and every element of the claim must be present in the reference.

Palmer discloses a self furling umbrella frame for a carotid filter. As shown in Figure 3, Palmer appears to disclose a capture device 32 with a plurality of structural members or struts 38, 40 that appear to make up a filter frame. The plurality of struts is apparently configured to expand the capture device 32 into a parachute-like structure. A filter material appears to be disposed across the struts.

In contrast, amended claim 1 recites, in part, a blood-impermeable wall defining a cavity, an elongate member extending through the cavity, a frame attached to the wall, and an actuation system for moving the frame between an expanded position and a contracted position. The actuation system comprises one or more actuating members which connect the frame to the elongate member.

Palmer is missing at least one of the elements of claim 1. Specifically, Palmer does not appear to disclose at least the one or more actuating members that connect the frame to the elongate member. For example, in Figure 3 of Palmer, Palmer does not appear to have actuating members that attach a filter frame of Palmer to an elongate member of Palmer. Thus, Palmer does not disclose each and every element of Palmer and Applicants respectfully assert that Palmer cannot anticipate claim 1. In addition, because they depend on claim 1 and because they recite additional patentably distinct elements, Applicants also assert that claims 8-10 are patentable.

Claims 2, 6, 7 and 17 were rejected as being unpatentable over Palmer. Applicants respectfully traverse this rejection. In the Office Action, some of the elements of claims 2 and 17 that are missing from Palmer were supplied by the Examiner by taking official notice that one of ordinary skill in the art would know to add these elements. In

addition, some of the elements of claims 6 and 7 were considered in the Office Action to be mere design changes and within the skill of a person of ordinary skill in the art. However, as mentioned above, Palmer does not appear to disclose each and every element of claim 1. Specifically, Palmer does not disclose at least the one or more actuating members that connect the frame to the elongate member, as recited in claim 1. The subject matter of claim 1 that is missing from Palmer is not supplied by another reference, through Official Notice, or from any other source. Thus, all elements of claim 1, and therefore all elements of dependent claims 2, 6, 7 and 17, are not present in the prior art as described in the Office Action, and Applicants respectfully assert that Palmer cannot render claims 2, 6, 7 and 17 obvious.

Further, Applicants respectfully assert that the use of Official Notice in rejecting claims 2 and 17 is improper. "If such notice is taken, the basis for such reasoning must be set forth explicitly. The examiner must provide specific factual findings predicated on sound technical and scientific reasoning to support his or her conclusion of common knowledge. See *Soli*, 317 F.2d at 946, 37 USPQ at 801; *Chevenard*, 139 F.2d at 713, 60 USPQ at 241. The applicant should be presented with the explicit basis on which the examiner regards the matter as subject to official notice and be allowed to challenge the assertion in the next reply after the Office action in which the common knowledge statement was made." M.P.E.P. §2144.03, Part B. When using official notice, "it is never appropriate to rely solely on "common knowledge" in the art without evidentiary support in the record, as the principal evidence upon which a rejection was based." M.P.E.P. §2144.03, Part A. In addition, if the Applicant specifically points out the errors in the use of official notice, the Examiner must either provide documentary evidence supporting the use of official notice or, if relying on personal knowledge, must provide an affidavit or declaration setting forth the facts and reasoning. See M.P.E.P/ §2143.03, Part C.

In the case of claim 2, an assertion was apparently made that Nitinol is used extensively in orthodontics, and thus one of ordinary skill in the art would use this in a coronary assist pump. However, the reasoning connecting the extensive use of Nitinol in orthodontics to the disclosure of Palmer has not been provided. Due to the lack of reasoning, it appears that the Examiner is relying almost entirely on the "common

knowledge” in the art, which, according to M.P.E.P. §2144.03, Part A, is an improper application of official notice. Thus, Applicants assert that all elements of claim 2 are not provided in the cited prior art, and claim 2 is patentable over Palmer.

In the case of claim 17, the Examiner has stated that “many devices introduced into the vasculature utilize antithrombotic agents.” Applicants assert that such a blanket statement does not provide a proper factual basis required for official notice. The Applicants must be provided with some factual evidence that this element of claim 17 is “common knowledge” in the art. Because no proper factual basis has been provided, the Applicants assert that either documentary evidence or an affidavit from the Examiner must be provided in order to substantiate the official notice used in this rejection.

Claims 3 and 5 were rejected based on 35 U.S.C. §103(a) as being unpatentable over Palmer in view of Breznock, U.S. Patent No. 6,638,253. Applicants respectfully traverse this rejection. In order for a combination of prior art references to render a claim obvious, the cited combination of prior art references must contain each and every element of the claim.

As mentioned above, Palmer does not contain each and every element of claim 1. In addition, Breznock does not disclose the elements of claim 1 that are missing from Palmer. Because this combination of references does not contain each and every element of claims 3 and 5, Palmer in view of Breznock cannot render claims 3 and 5 obvious.

Claim 4 was rejected based on 35 U.S.C. §103(a) as being unpatentable over Palmer in view of Bonutti, U.S. Patent No. 5,163,949. Applicants respectfully traverse this rejection. In order for a combination of prior art references to render a claim obvious, the prior art references must contain each and every element of the claim.

As mentioned above, each and every element of claim 1 is not disclosed in Palmer. In addition, Bonutti does not supply the portions of claim 1 that are missing from Palmer. Specifically, neither Palmer nor Bonutti disclose the one or more actuating members that connect the frame to the elongate member, as recited in claim 1. Because each and every element of claim 1 is not present in the combination of Palmer and Bonutti, each and every element is not present in dependent claim 4. Thus, each and every element of claim 4 is not present in this combination of references, and this combination cannot render claim 4 obvious.

Claims 18-20, 24 and 25 were rejected based on 35 U.S.C. §102(b) as being anticipated by Schiff, U.S. Patent No. 4,522,195. Applicant respectfully traverses this rejection. In order for a reference to anticipate a claim, each and every element of the claim must be present in the reference.

Schiff discloses an apparatus for left heart assist. The apparatus can apparently comprise a balloon member and an umbrella member. As stated in column 6, lines 10-15, the function of the prior art balloon of Figure 2 is described as follows: "When the intra-aortic balloon 12 is properly positioned through either femoral artery, the balloon 12 is operated by pulsatile pressure generating means (not shown) for inflating the balloon 12 during diastole and for deflating balloon 12 during systole in order to decrease left ventricular pressure and heart work." The balloon can apparently create positive or negative pressure at times during the heart pumping cycle in order to make it easier for the heart to pump blood. See, for example, column 6, lines 53-60. Further, the balloon 22 of Figure 3 is said to operate in much the same manner as the balloon of prior art Figure 2. See column 7, lines 5-6.

Schiff appears to introduce an umbrella that can apparently help in eliminating the harmful effects of retrograde flow around the balloon. See for example, column 6, lines 53-64. The umbrella apparently opens up when blood flows across the umbrella from the closed end toward the open end of the umbrella. Thus, blood flow in this direction is allowed substantially unhindered. The umbrella can then apparently open back up when the blood flow is reversed (when the blood flows in a direction from the open toward the closed end of the umbrella). With the umbrella in an open position, retrograde flow can be diminished or eliminated. This operation of the umbrella is described, for example, at column 7, lines 34-60. Thus, the umbrella of Schiff appears to operate as a check valve mechanism for selectively allowing blood flow through the aortic arch. In at least one embodiment, the umbrella can have stiffeners 28, 29, which can apparently help support the shape of the umbrella.

In contrast, claim 18 recites an intravascular pump with a flexible wall, the wall defining a pumping chamber. The pump further comprises "a pumping mechanism including a frame attached to the wall." The flexible wall defines the pumping chamber, and a pumping mechanism is attached to the wall.

The Office Action apparently equates the umbrella of Schiff with the pumping chamber of claim 18, and the stiffeners 28, 29 of Schiff with the frame of claim 18. Applicants respectfully traverse this characterization of Schiff. Schiff does not appear to disclose a structure that could be described as a wall making up a pumping chamber, where a frame is attached to the wall. The umbrella of Schiff that is equated with the pumping chamber of claim 18 simply changes configuration in response to the direction of the blood flow in the aorta. It does not appear to actually be pumping blood through the aorta. As mentioned above, the umbrella appears to act more like a check valve than a pump. Thus, the umbrella of Schiff should not be described as a wall defining a pumping chamber, with a frame attached to the wall. Because each and every element of claim 18 is not disclosed in Schiff, Applicants respectfully assert that Schiff cannot anticipate claim 18. Because they depend on claim 18 and because they contain additional patentably distinct elements, Applicants also assert that claims 19, 20, 24 and 25 are patentable over Schiff.

Claims 21-23 were rejected based on 35 U.S.C. §103(a) as being unpatentable over Schiff in view of Breznock. Applicants respectfully traverse this rejection. In order for a combination of prior art references to render a claim obvious, the prior art references must contain each and every element of the claim.

As mentioned above, Schiff does not contain each and every element of claim 18. In addition, Breznock does not appear to disclose the elements of claim 18 that are missing from Schiff, and thus this combination of references does not contain each and every element of claims 21-23. Because this combination of references does not contain each and every element of claims 21-23, Schiff in view of Breznock cannot render claims 21-23 obvious.

Claim 26 was rejected based on 35 U.S.C. §103(a) as being unpatentable over Schiff in view of Choy et al., U.S. Patent No. 4,771,765 (hereinafter "Choy"). Applicants respectfully traverse this rejection. In order for a combination of prior art references to render a claim obvious, the prior art references must contain each and every element of the claim.

As mentioned above, Schiff does not contain each and every element of claim 18. In addition, Choy does not disclose the elements of claim 18 that are missing from Schiff,

and thus this combination of references does not disclose each and every element of claim 26. Because this combination of references does not contain each and every element of claim 26, Schiff in view of Breznock cannot render claim 26 obvious.

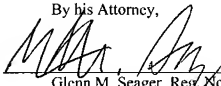
Reexamination and reconsideration are respectfully requested. It is submitted that all pending claims are currently in condition for allowance. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at 612-677-9050.

Respectfully submitted,

BRYAN LEASURE

By his Attorney,

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Glenn M. Seager, Reg. No. 36,926  
CROMPTON, SEAGER & TUFTE, LLC  
1221 Nicollet Avenue, Suite 800  
Minneapolis, Minnesota 55403-2420  
Tel: (612) 677-9050